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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,793

09/06/2006

Martin Edward Lee Pickford

1450-02100

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7590

10/14/2009

Tod T. Tumey

P.O. BOX 22188

HOUSTON, TX 77227-2188

EXAMINER

LEADER, WILLIAM T

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,793	Applicant(s) PICKFORD ET AL.	
	Examiner WILLIAM T. LEADER	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/6/06; 10/26/07; 11/28/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt of the preliminary amendment filed on January 26, 2009, is acknowledged. New claims 7-12 have been added. Claims 1-12 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1, line 8 recites a step of anodizing at a voltage above 50V. Lines 11-14 recite that the magnitude of the anodizing voltage is such that the anodizing generates a dense hard surface layer and also shallow pits in the surface layer which are filled with a somewhat softer and more porous material. The recitation in lines 11-14 appears to indicate that there is some voltage value or range other than or within the range recited in line 8 that must be chosen to produce the recited results. Thus, as written, the claim appears to recite a sub-range within the range of above 50V recited in line 8. Similarly, lines 8-9 of claim 1 recite a period of at least 30 minutes. The recitation in lines 11-14 appears to indicate that there is some period of time other than or within the range recited in lines 8-9 that must be utilized to produce the recited results. Consequently, the scope of the claim is not clear. Additionally, it is not clear what values of current density and electrolyte concentration are included within the scope of the claims. Independent claim 7 includes similar limitations.

5. Voltage and current are related by Ohm's Law, $E = I \times R$, where E is voltage, I is current, and R is resistance. Line 10 appears to recite that a magnitude of current density is chosen independent of voltage. It is not clear how current density can be set in a manner which is independent of the voltage recited in line 8. It appears that if a voltage above 50 V is applied, a given value of current density will result.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. At page 2, lines 10-15 of applicant's specification it is stated "Performing the anodising at a voltage above 50 V has two effects: it initially generates a dense hard surface layer whose thickness is primarily determined by the voltage, and it then generates shallow pits in the surface which are filled with a somewhat softer and more porous material." The description of the characteristics of the implant produced by the anodization step described in this portion of the specification is the same as that recited in claims 1 and 7. The only criteria for achieving these characteristics set forth in the specification is anodizing at a voltage above 50V. The claim language appears to indicate that parameters of current density, electrolyte concentration, the duration of anodizing, and magnitude of the anodizing voltage must all be chosen such that the recited results are achieved. To the extent that

parameters other than voltage as described at page 2, lines 10-15 must be set to obtain the recited results, the specification is not considered to be enabling for the claims as written.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickford et al (WO 03/089023) in view of O'Brien et al (US 7,488,343) and Rosenberg et al (US 5,185,075).

11. The Pickford et al publication (hereinafter Pickford) is directed to the manufacture of metal implants. The implant may be made of titanium alloy which is very strong and relatively light (page 1, lines 11-12). The implant comprises a metal substrate and a surface layer that is integral with the metal substrate and which incorporates a biocidal metal (page 1, lines 25-29). The integral surface layer may be generated by growing the layer from the metal itself, for

example by an anodizing process (page 1, line 34-36). Silver is the preferred biocidal metal (page 2, lines 25-28). In an example at page 5, lines 1-23, a hip implant made of titanium alloy was anodized in a 12 wt% solution of phosphoric acid for 2 hours at a maximum voltage of 10V so as to form a surface coating of titanium phosphate. Subsequently, the implant was immersed in an aqueous solution of silver nitrate. This results in the formation of some silver phosphate in the titanium phosphate coating.

12. The process recited in independent claims 1 and 7 differs from the process of Pickford by reciting anodizing at a voltage above 50V. The O'Brien et al patent (hereinafter O'Brien) is directed to the production of medical devices such as stents which may be implanted. The devices have a generally tubular member which includes a porous structure including an oxide of titanium (column 1, lines 50-54). Titanium is highly desirable because of its high biocompatibility (column 5, lines 33-34). Figures 3A and 3B show the porous morphology that is formed by anodization (column 5, lines 49-50). The depth, diameter and spacing of the elements can be controlled by controlling process parameters such as the process time, composition of the chemical bath, circuit voltage, and process temperature (column 6, lines 5-10). Higher temperatures, higher acid concentrations and longer anodization time periods can produce more porous and, in some cases, softer coatings (column 6, lines 14-16). . O'Brien teaches higher voltages yield larger openings. The voltage is typically in the range of about 5 to about 100V (column 6, lines 20-24). The chemical bath can be an acid solution such as a 20 vol% phosphoric solution (column 6, lines 27-32). In the Examples at columns 11 and 12, O'Brien used a 20% phosphoric acid solution and applied voltages ranging from 5 to 100 volts. The pores produced in the anodizing step may be filled with a therapeutic agent. For example a

device with larger pores can contain one type of therapeutic agent, while another device with smaller pores can contain a different type of therapeutic agent. The two different therapeutic agents can be delivered into the body at different rates (column 13, lines 55-63).

13. The Rosenberg et al patent (hereinafter Rosenberg) is directed to a process for anodizing titanium and titanium alloy articles. Table 1 shows that a 5-25 vol% solution of phosphoric acid is a useful anodizing electrolyte. Rosenberg recognizes that halides may be harmful to the anodizing process and suggests the addition of silver nitrate to suppress free chloride. When using silver nitrate for this purpose, the appearance of the yellow silver phosphate signals the excess of silver over halide (column 5, lines 58-63). In example 1 an anodizing voltage of 100 V was applied.

14. The prior art of record is indicative of the level of skill of one of ordinary skill in the art. It would have been obvious at the time the invention was made to have utilized a voltage of greater than 50V to anodize a titanium implant in a process such as that of Pickford because O'Brien teaches that voltages ranging from lower than that used by Pickford to greater than 50V may be successfully used in forming a porous oxide layer on a titanium implant which may be filled with a bioactive material, and Rosenberg shows that a voltage of 100V may be used to form a titanium oxide layer using a phosphoric acid anodizing bath. As shown by Pickford, process parameters such as voltage may be varied to obtain an oxide layer with the desired characteristics. Choice of a value from within the voltage range disclosed by Pickford would have been obvious. See MPEP 2144.05.

15. With respect to claims 2 and 8, Pickford discloses the use of silver as a biocidal material.

16. With respect to claims 3, 4, 9 and 10, Pickford, O'Brien and Rosenberg all disclose that phosphoric acid in a concentration within the range of 5 to 20 wt% may be used as an anodizing electrolyte.
17. With respect to claims 5 and 11, Rosenberg discloses the presence of small amount of chloride ions.
18. With respect to claims 6 and 12, O'Brien and Rosenberg suggest anodizing at a voltage greater than 50V. The use of such a voltage would be expected to produce shallow pits that extend through the surface layer into the metal substrate in the same manner as in applicant's process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM T. LEADER whose telephone number is (571) 272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Leader/
September 30, 2009

/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795